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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/685,058	10/14/2003	Wallace J. Gardner	632P002	5709

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EXAMINER	
KIM, JENNIFER M	

ART UNIT	PAPER NUMBER
1617	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/685,058	GARDNER, WALLACE J.	
	Examiner	Art Unit	
	Jennifer Kim	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 February 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *7-12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *7-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The amendment filed February 6, 2007 have been received and entered into the application.

Action Summary

The rejection of claims 7-12 are rejected under 35 U.S.C. 112, first paragraph is hereby expressly withdrawn in view of Applicant's amendment.

The rejection of claims 7, 8, 10 and 11 under 35 U.S.C. 103(a) as being unpatentable over McNamara et al. (U.S.Patent No. 5,223,248) is hereby expressly withdrawn in view of Applicant's amendment.

With regard to the rejection of claims 7-12 under 35 U.S.C. 103(a) as being unpatentable over Wu et al. (WO 2004/093876A2), the rejection of independent claim 7 and claims 8 and 9 depend from claim 7, is hereby expressly withdrawn in view of Applicant's amendment of independent claim 7. However, the rejection of independent claim 10 and claims 11 and 12 depend from claim 10 is being maintained for the reasons stated in the previous Office Action. This rejection (claims 10-12) is modified to address the newly added limitation.

Applicant's amendment necessitated additional rejections presented in this Office action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 7, 8, 10 and 11 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 7, 8, 10 and 11 are drawn to a method of reducing plaque formation on teeth or tooth decay of mammal comprising brushing with a composition comprising an effective amount of **a tetracycline that has not been chemically modified** in a liquid vehicle. The claims thus exclude a broad genus of a tetracycline that have been chemically modified. The instant specification neither describes all tetracyclines that are not chemically modified nor describes all the tetracyclines that are chemically modified. Accordingly, the instant specification does not provide a basis for one of skill in the art to envision the structural/functional characteristics of such tetracyclines that have been chemically modified to be excluded. The premise for the limitation to a tetracycline that has not been chemically modified appears to be derived from the observation in the instant specification of a tetracycline which **has not been chemically modified to eliminate antimicrobial efficacy**. (page 2, lines 17-22). The specification does not

however, indicate why one should assume, based on the disclosure of the employment of the specific tetracyclines (not chemically modified to eliminate antimicrobial efficacy), that new concept that any species of the broad genus of a tetracyclines that have been chemically modified is to be excluded. It is noted that the tetracycline molecule is amendable to substantial modification without losing its antibiotic properties. Applicant have not described any structure, formula or definition of "a tetracycline that have been chemically modified" to be excluded. Applicant's exclusion of a chemically modified tetracycline genus, like a description of a chemical species, requires a precise definition, such as a structure or formula fully describe of so that it is sufficiently understood what is to be excluded from what is claimed.

Given this lack of description of a sufficient number of the representative species encompassed by the genus of the claim, the specification fails to described the claimed invention in such full, clear, concise, and exact terms regarding the chemical structure-function relationship that a skilled artisan would recognize that Applicants were in possession of the claimed invention of a **broad genus** of **" a tetracycline that is chemically modified**" now excluded by instant claims.

This is a New Matter rejection.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 7-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With regard to claims 7-12 the phrase "**a tetracycline that has not been chemically modified**" is indefinite. It is not clear what tetracyclines are intended because the phrase contradicts dependent claims 9 and 12. One of ordinary skill in the art could not ascertain and interpret the metes and bounds of the term "chemically modified" because one of ordinary skill in the art would clearly recognize that Applicant's active agent set forth in claims 9 and 12, **doxycycline, is a chemical modified form of tetracycline.**

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 10-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wu et al. (WO 2004/093876A2) of record.

Wu et al. teach compositions for controlling oral pathogens in **mammals** including **humans,** comprising tetracyclines, including **doxycycline**. (abstract, page 5, lines 4-10). Wu et al. teach that **dental plaque** is frequently associated with oral diseases, including **dental caries** and that plaque control can be achieved by mechanical (e.g. **brushing** and flossing) or chemical means. (page 1 last sentence –

page 2 line 6). Wu et al. teach that the composition can be administered in **liquid form** with a **liquid carrier**, such as **water**. (page 29, lines 10-30, particularly, lines 26-27).

Wu et al. do not teach the **actual illustration** comprising brushing with a tetracycline (doxycycline) composition in order to reduce plaque formation/tooth decay in a mammal and do not expressly teach the employment of a tetracycline that has not been chemically modified.

It would have been obvious to one of ordinary skill in the art to employ the composition comprising tetracycline/doxycycline taught by Wu et al. for reducing tooth decay in a mammal by brushing because Wu et al. teach that the composition comprising tetracycline/doxycycline is useful for reducing dental plaque and dental caries leading and causing tooth decay and that mechanical means of brushing is also effective in reducing dental plaque/caries. One would have been motivated to make such a modification in order to obtain an expected additive benefit of both chemical means comprising tetracycline/doxycycline and mechanical means with brushing. With regard to the limitation of "a tetracycline that has not been chemically modified" such is obvious because Wu teaches a composition for controlling oral pathogens comprising tetracyclines including **doxycycline** as recited in Applicant's claim 12. Since Wu's compound and the invention as claimed are identical, the properties of the same active agent, doxycycline employed by Wu obviously possess the same chemical/physical properties of "not chemically modified tetracycline", because a compound and its properties are inseparable.

Claims 7-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wu et al. (WO 2004/093876A2) of record in view of Goldemberg et al. (U.S.Patent No. 4,666,708).

Wu et al. teach compositions for controlling oral pathogens in **mammals,** including **humans,** comprising tetracyclines, including **doxycycline.** (abstract, page 5, lines 4-10). Wu et al. teach that **dental plaque** frequently is associated with oral diseases, including **dental caries** and that plaque control can be achieved by mechanical (e.g. **brushing** and flossing) or chemical means. (page 1 last sentence – page 2 line 6). Wu et al. teach that the composition can be administered in **liquid form** with a **liquid carrier**, such as **water**. (page 29, lines 10-30, particularly, lines 26-27). Wu teach that the composition can be formulated in a conventional manner using one or more physiologically acceptable carriers comprising excipients and auxiliaries that facilitate processing of the active agents into preparations which can be used pharmaceutically. (page 29, lines 5-10).

Wu et al. do not teach an **actual illustration** comprising brushing a tetracycline (doxycycline) composition in order to reduce tooth decay in a mammal, the "chemically modified" tetracycline and a composition comprising at least about 35% alcohol.

Goldemberg et al. teach that a dental hygiene composition such as a dental rinse comprising about 5% to about 35% alcohol is useful as a dental rinse. Goldemberg et al. teach that the composition loosens plaque present on dental surfaces and renders them more amenable to removal of plaque during brushing with a conventional dentifrice. (abstract, column 1, lines 9-15, claim 17). Goldemberg et al. teach that

employment of ethanol (alcohol) in a dental rinse imparts antiseptic properties therein. (column 5, lines 59-65).

It would have been obvious to one of ordinary skill in the art to incorporate an alcohol content up to 35% in Wu's tetracycline/doxycycline formulation for reducing plaque formation in a mammal by brushing because Wu et al. teach that the composition comprising tetracycline/doxycycline is useful for reducing dental plaque, and that mechanical means of brushing are effective in reducing dental plaque; and because Goldemberg et al. teach that dental rinse comprising an alcohol content up to 35% is useful for dental hygiene product because it loosen plaque present on dental surfaces and renders them more amenable to removal during brushing. On of ordinary skill in the art would have been motivated to combine Wu's tetracycline/doxycycline composition with Goldemberg et al's dental rinse for reducing plaque formation by brushing in order to achieve at least an additive effect in reducing plaque. The motivation for combining the components flows from their individually known common utility for reducing dental plaque (see In re Kerkhoven, 205 USPQ 1069(CCPPA 1980)). With regard to the limitation of "a tetracycline that has not been chemically modified" such is obvious because Wu teaches a composition for controlling oral pathogens comprising tetracyclines, including **doxycycline,** as recited in Applicant's claim 9. Since Wu's compound and the invention as claimed are identical, the properties of the active agent, doxycycline employed by Wu possesses same chemical/physical properties of "not chemically modified tetracycline" because a compound and its properties are inseparable.

For these reasons the claimed subject matter is deemed to fail to patentably distinguish over the state of the art as represented by the obvious combination of the cited references. The claims are therefore properly rejected under 35 U.S.C. 103.

None of the claims are allowed.

Response to Arguments

Applicant's arguments filed February 6, 2007 have been fully considered but they are not persuasive. Applicant argues that the compositions of Wu et al. include, as a necessary component, berberine in order to potentiate the antimicrobial action of the antibiotic. This is not persuasive because Applicant's claims, drawn to a method of reducing plaque formation or reducing tooth decay ... "**comprising",** does not limit the claims to a utilization of tetracycline as a solo agent. Further, berberine, present in Wu et al's composition and potentiating antimicrobial action of the antibiotic indicates that the antibiotics utilized in Wu et al. possess an antimicrobial action that it are enhanced by adding berberine. The berberine compound is only needed to potentiate the antimicrobial action already present in the antibiotics utilized in Wu et al. Therefore, the cited prior art properly renders the claim obvious. Applicant argues that Wu et al. do not disclose or suggest brushing teeth with a composition comprising at least about 35% alcohol and a plaque formation reducing effective amount or a tooth decay reducing effective amount of a tetracycline that has not been chemically modified in a

liquid vehicle as is now claimed. This is not persuasive because applicant's new limitation of at least about 35% alcohol is within the range of alcohol content routinely found in dental hygiene compositions useful for having antiseptic properties as taught by Goldemberg et al. The antiseptics such as alcohol are advantageous in dental hygiene compositions because they impart antiseptic properties to the dental formulations. Therefore, it would have been obvious to one of ordinary skill in the art to incorporate alcohol with the amount routinely found in the oral dental hygiene product into Wu et al's formulation in order to achieve at least an additive effect in reducing plaque. Moreover, with regard to the limitation of "a tetracycline that has not been chemically modified", such is obvious because Wu teaches a composition for controlling oral pathogens comprising tetracyclines including **doxycycline** as recited in Applicant's claims 9 and 12. Since Wu's compound and the invention as claimed are identical, the properties of the active agent, doxycycline employed by Wu obviously possesses the same chemical/physical properties of a "not chemically modified tetracycline" because a compound and its properties are inseparable.

Thus, the claims fail to patentably distinguish over the state of the art as represented by the obvious combination of the cited references.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kim whose telephone number is 571-272-0628. The examiner can normally be reached on Monday through Friday 6:30 am to 3 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jennifer Kim
Patent Examiner
Art Unit 1617

Jmk
April 30, 2007